

### **DETAILED ACTION**

A request for continued examination under 37 CFR 1.114 was filed in this application after appeal to the Board of Patent Appeals and Interferences, but prior to a decision on the appeal. Since this application is eligible for continued examination under 37 CFR 1.114 and the fee set forth in 37 CFR 1.17(e) has been timely paid, the appeal has been withdrawn pursuant to 37 CFR 1.114 and prosecution in this application has been reopened pursuant to 37 CFR 1.114. Applicant's submission filed on 12 May 2008 has been entered.

Applicants' response, filed 12 May 2008, has been fully considered. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

Claims 1-20 are currently pending.

Claims 10 and 12 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected species, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 20 April 2006

Claims 1-9, 11, and 13-20 are examined herein.

### **Claim Objections**

Claims 1 and 5 are objected to because of the following informalities:

Claim 1, as amended, recites at step (d) "calculation of the dose". This is grammatically incorrect in terms of the rest of the claim which recites "performing", "adjusting" checking" etc.. The step should be amended to recite "calculating the dose".

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Claim 5 recites, “wherein effective treatment regimen is defined”. The is grammatically incorrect and should read, “wherein **an** effective treatment regimen is defined”.

Appropriate correction is required.

**Claim Rejections - 35 USC § 112-2<sup>nd</sup> paragraph**

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-9, 11, and 13-20 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1, as amended, recites, “and the phase I clinical trial is performed in parallel with performing computer simulations of the computer model”. It is unclear as to what the simulations of a computer model are. Are the simulations run on the model from step (a)? Clarification is requested.

Claim 1, as amended, recites, “ wherein the at least a single dose of step (b) is incrementally increased”. It is unclear as to what the single does of step (b) is. Is it the dose of the drug from step (a) or some other dose? Clarification is requested.

Claim 11 recite, “wherein the decision is based on a prediction of efficacy profile of the new drug”. There is insufficient antecedent basis i the claim for the "new" drug, as no new drug was previously recited. Clarification is requested.

Claims 15-20 recite, “wherein the computer model is an in silico patient that interacts with the results of the pre-clinical trials”. It is unclear as to with what about the preclinical trials

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the in silico patient is interacting. Further, is the model the patient that interacts or does the model itself interact or does the model represent an in silico patient? Clarification is requested.

Claims 18-20 recite, "wherein the prediction". There is insufficient antecedent basis in the claim, as no "prediction" was set forth previously. Clarification is requested.

Claims 18-20 recite, "wherein the at least one clinical trial is performed in parallel with computer simulation of a computer model" or "in parallel with computer simulations of a computer model", respectively. It is unclear as to how one performs computer simulations of a computer model. Perhaps Applicant intends the claim to read "performing computer simulations on a computer model" or "performing simulations using a computer model". Clarification is requested.

### **Conclusion**

No claims are allowed.

The outstanding rejections over claims 15-17 under 35 USC 102 (b) over Iliadis et al. have been withdrawn in view of Applicant's arguments and the amendments to the claims adding the "in silico patient" model.

### **Inquiries**

Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the PTO Fax Center. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993) (See 37 CFR § 1.6(d)). The Central Fax Center Number is (571) 273-8300.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lori A. Clow, Ph.D., whose telephone number is (571) 272-0715. The examiner can normally be reached on Monday-Friday from 10 am to 6:30 pm.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marjorie Moran can be reached on (571) 272-0720.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

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June 25, 2008

/Lori A. Clow, Ph.D./

Primary Examiner, Art Unit 1631